

Applicant : Kevin R. Heath  
Serial No. : 10/751,749  
Filed : January 5, 2004  
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Attorney's Docket No.: 10527-118005 / 92-P0049(08)

Amendments to the Drawings:

The attached sheet of drawings includes Figure 7.

In Figure 7, layers 4', 9', 8' are shown.

Attachments following last page of this Amendment:

Replacement Sheet (1 page)

### **REMARKS**

In response to the Office Action mailed February 3, 2006, Applicant has amended FIG. 2 and FIG. 2a; and claims 39, 40, and 46. Claims 39-46, of which claim 39 is independent in form, are presented for examination.

### **Priority**

According to the Examiner, claims 39-46 are not entitled to priority to the prior application because the disclosure of the prior-filed application, Application No. 09/924,275 and prior applications fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. § 112 for one or more claims of this application. In particular, according to the Examiner, the application does not support the terminology of "third metal portion" in the claims (e.g., claim 39). Applicant traverses.

The present application claims priority through a series of continuation applications to a CIP application filed on July 8, 1992. The CIP application clearly discloses that the outer member (e.g., the outer material) includes a metal (*see, e.g.*, page 13, lines 12-14; and page 13, lines 32-35) and that the core material includes a metal (*see, e.g.*, page 14, lines 10-12). The CIP application further discloses that the stent can include layers of less dense outer material and more dense core material to form a multi-composite system of three layers or more (*see, e.g.*, page 15, lines 4-7). Thus, as both outer and core materials include metals and the outer member can include more than one layer, a person of ordinary skill in the art would have readily recognized that the outer member can include layers of outer material including a third layer, as amended, that is metallic.

According to the Examiner, the disclosure does not support portions of the same material as required by claim 40. However, as explained above, the outer member can include many layers (*see, e.g.*, page 15, lines 4-7) and the CIP application also states that the inner and outer metals may be the same metals (*see, e.g.*, page 13, lines 7-8). As any layer encompassed by an exposed outer metal can be interpreted as an inner layer (*see, e.g.*, page 6, lines 30-32), a person of ordinary skill in the art would have readily recognized that the outer member including many layers can include a third metal layer and a first metal layer, where one layer is the interior,

exposed layer and the other layer is the exterior, exposed layer, that are formed of the same material (i.e., the first metal), as amended.

In light of the above remarks, the subject matter as amended is entitled to a filing date of at least July 8, 1992. Applicant requests that the objection be reconsidered and withdrawn.

### **Drawings**

Applicant has added Figure 7 to show the third metal layer, so the objection should be withdrawn.

### **Specification**

The Examiner has objected to the amendment filed 03/04/2005 because it allegedly introduces new matter into the disclosure of the invention. Applicant traverses. According to the Examiner, "the third metal portion is formed of said first metal" of claim 40 is not disclosed, and a "third metal portion" of claims 39-46 is not disclosed such that a person of ordinary skill in the art would recognize possession of the claimed limitation. As discussed above with regard to priority, the application as filed discloses that the outer member can include many layers (*see, e.g.,* page 15, lines 4-7) and that the inner and outer metals may be the same metals (*see, e.g.,* page 13, lines 7-8). As any layer encompassed by the exposed metal can be interpreted as an inner layer (*see, e.g.,* page 6, lines 30-32), a person of ordinary skill in the art would have readily recognized that the outer member including many layers can include a third metal layer and a first metal layer, where one layer is the interior layer and the other layer is the exterior layer, that are formed of the same material (i.e., the first metal), as claimed. With regard to objection concerning the "third metal portion", as explained above, the CIP application clearly discloses that the outer member (e.g., the outer material) includes a metal (*see, e.g.,* page 13, lines 12-14; and page 13, lines 32-35) and that the core material includes a metal (*see, e.g.,* page 14, lines 10-12). The CIP application further discloses that a stent can include layers of less dense outer material and more dense core material to form a multi-composite system of three layers or more (*see, e.g.,* page 15, lines 4-7). Thus, both outer and core materials include metals, and the outer member can include greater than one layer including a third layer, as amended. As such, a

person of ordinary skill in the art would have readily recognized that the third layer is metallic, as supported by the application.

According to the Examiner, a third metal portion associated with a sheet of claim 46 is not supported. The CIP application to which the present application claims priority discloses that the stent may also be in the form of a metal member configured as other than a composite filament form, such as a composite sheet form (*see, e.g.*, page 16, lines 8-10). Thus, a person of ordinary skill in the art would have recognized that the subject matter as amended pertains to stents of both filament and sheet forms. Therefore, Applicant requests that the objection be reconsidered and withdrawn.

#### **Claim Rejections – 35 U.S.C. § 112**

The Examiner has rejected claims 39-46 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. As discussed above, the subject matter as claimed is supported by the specification of the application as filed (*see, e.g.*, page 15, lines 4-7; page 13, lines 7-8; page 6, lines 30-32; page 13, lines 12-14; page 13, lines 32-35; page 14, lines 10-12; page 15, lines 4-7; and page 16, lines 8-10), and a person of ordinary skill in the art would have readily recognized that the application had possession of the claimed invention, as amended. Therefore, Applicant requests that the rejection be reconsidered and withdrawn.

The Examiner rejected claims 39-46 under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicant amended the claims to recite medical stents including a first metal layer, a second metal layer, and a third metal layer. Therefore, Applicant requests that the rejection be withdrawn.

#### **Double Patenting**

The Examiner rejected claim 39 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 23 of U.S. Patent No. 6,287,331. Applicant requests that this provisional rejection be held in abeyance until the claim is found otherwise allowable.

#### **Claim Rejections – 35 U.S.C. § 102**

The Examiner rejected claims 39-44 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,387,123 ("Jacobs"). As discussed above, the claimed subject matter is entitled to a priority date of at least July 8, 1992. The filing date of Jacobs (October 13, 1999) is after Applicant's priority date of July 8, 1992. Therefore, Jacobs is not prior art to the claimed subject matter and the rejection should be withdrawn.

### **Claim Rejections – 35 U.S.C. § 103**

The Examiner rejected claims 45 and 46 under 35 U.S.C. § 103(a) as being unpatentable over Jacobs. As discussed above, the filing date of Jacobs (October 13, 1999) is after Applicant's priority date of July 8, 1992. Therefore, Jacobs is not prior art to the claimed subject matter and the rejection should be withdrawn.

The Examiner rejected claims 39-42 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,197,978 ("Hess"). As amended, claims 39-42 recite an implantable medical stent including a metal member having a cross-sectional thickness of at least 0.0075 inch or less formed of at least two different metals, a first metal layer, a second metal layer, and a third metal layer, wherein the density of the second metal is greater than the density of the first metal, and the second metal enhances the radiopacity of the metal member.

Hess discloses a reinforcing member 44 connected with a recoverable member 42, and that the reinforcing member 44 can be, for example, stainless steel, gold, tantalum (*see, e.g.*, Hess, column 8, lines 33-37). As acknowledged by the Examiner, Hess does not disclose the thickness of a metal member, and there is no suggestion to modify Hess's stent to have the claimed cross-sectional thickness other than the Examiner's official notice, to which Applicant does not concede. Hess is also silent on using a high density metal that enhances the radiopacity of the metal member. For example, Hess does not provide the thickness of reinforcing member 44 so there is no indication that the reinforcing member actually enhances the radiopacity of a metal member. Rather, it appears that reinforcing member 44 is used as a structural reinforcing interface between two layers of recoverable member 42. As a result, one having ordinary skill in the art would not have been motivated to modify Hess's stent to arrive at the claimed subject matter, as amended. Therefore, Applicant requests that the rejection be withdrawn.

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In light of the above remarks, Applicant believes the claims are in condition for allowance, which action is requested.

Enclosed is a Petition for Extension of Time with the fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: August 21, 2006



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